K131765

DEC 2 0 2013

510(k) Summary of Safety and Effectiveness

ECOM™ Endotracheal Cardiac Output Monitoring System

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number _____ as of June 14, 2013.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Lisa Anderson
Manager, Regulatory Affairs
T: (315) 624-3371
F: (315) 624-3225

C. Device Name

Proprietary Name:	ECOM™ Endotracheal Cardiac Output Monitor System
Common Name:	Plethysmograph, impedance
Classification Name:	Impedance plethysmograph
Regulation Number:	870.2770
Product Code:	DSB
Regulatory Class:	II
Panel:	Cardiovascular

D. Predicate Device

Device Name:	ECOM CV4 Endotracheal Cardiac Output Monitor
Company Name:	ConMed Corporation via acquisition of Imagyn Medical Technologies
510(k):	K032491

E. Device Description

The ECOM Endotracheal Cardiac Output Monitor System consists of a monitor, an endotracheal tube and various accessories. The system applies a high frequency, low amplitude electrical current to a series of electrodes applied to the endotracheal tube. The resulting signals, when used in conjunction with an arterial pressure signal, allow for the calculation and display of Cardiac Output (CO), Cardiac Input (CI), Stroke Volume (SV), Stroke Volume Variation (SVV), Heart Rate (HR), Systemic Vascular

Resistance (SVR), Systemic Vascular Resistance Index (SVRI), and systolic, diastolic and mean blood pressures.

F. Intended Use / Indications for Use

The ECOM Endotracheal Cardiac Output Monitor System is intended for the monitoring of cardiac output by impedance cardiography while providing airway management by oral intubation with an ECOM Endotracheal Tube. The ECOM System is indicated for use in patients who are expected to be intubated for 24 hours or less and in whom an arterial pressure line is used.

The ECOM System displays the R-Wave Detection and the Impedance Waveforms as well as the patient's Cardiac Output (CO), Stroke Volume (SV), Heart Rate (HR), Systolic and Diastolic Pressure.

G. Non-clinical Performance Testing

Non-clinical bench testing demonstrated the ConMed ECOM Endotracheal Cardiac Output Monitor System is substantially equivalent to the predicate with regard to intended use, materials, technology, and performance. Design verification testing, including software validation, demonstrates the system complies with the applicable sections of IEC 60601-1:1988/A1:1991/A2:1995, IEC 60601-1-1:2000, IEC 60601-1-2:2001/A1:2004 and IEC 60601-1-4:2000. Material analysis demonstrates the patient contacting materials comply with the requirements of ISO 10993-1:2009.

H. Substantial Equivalence

The differences between the predicate and the modified design do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the ConMed ECOM Endotracheal Cardiac Output Monitor System is safe and effective for the intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

ConMed Corporation
Ms. Lisa Anderson
Manager, Regulatory Affairs
525 French Road
Utica, NY 13502

Re: K131765
Trade/Device Name: ECOM® Endotracheal Cardiac Output Monitor System
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: November 19, 2013
Received: November 20, 2013

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131765

510(k) Number (if known): _____

Device Name: ECOM® Endotracheal Cardiac Output Monitor System

Indications for Use:

The ECOM Endotracheal Cardiac Output Monitor System is intended for the monitoring of cardiac output by impedance cardiography while providing airway management by oral intubation with an ECOM Endotracheal Tube. The ECOM System is indicated for use in patients who are expected to be intubated for 24 hours or less and in whom an arterial pressure line is used.

The ECOM System will display the R-Wave Detection and the Impedance Waveforms as well as the patient's Cardiac Output (CO), Stroke Volume (SV), Heart Rate (HR), Systolic and Diastolic Pressure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.12.20 14:01:42 -05'00'